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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,972	05/11/2001	BARRY ROSS MATTHEWS	017227/0171	7954

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EXAMINER	
FUBARA, BLESSING M	
ART UNIT	**PAPER NUMBER**
1618	

DATE MAILED: 06/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/786,972	MATTHEWS ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *3/30/06*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of request for continued examination, remarks and amendment filed 3/30/06. Claim 1 is amended. Claims 1-11 are pending.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 3/30/06 has been entered.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inhibiting the activity of cobra venom and bee venom, does not reasonably provide enablement for inhibiting the activity toxins or toxic peptides from all animals, plants, microbial origins, bacterial, protozoal and fungal infections. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly

connected, to use the invention commensurate in scope with these claims. This is scope of enablement.

For the rejection above, the following factors of the In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988) decision are considered pertinent as to undue experimentation:

1) Nature of the invention.

2) State of the prior art.

3) The predictability or lack thereof in the art.

4) Amount of direction and guidance provided/present.

5) Presence or absence of working examples.

6) Breadth of claims.

7) Quantity of experimentation needed.

- **Nature of the invention**

The claims are directed to method of inhibiting the activity of toxic materials and the method comprises administration of an effective amount of dendrimer.

The specification at page 9, lines 4-10describes toxic materials as describes "toxic materials or substances" as toxins of biological (animal, plant, microbial or viral) origin, including but not limited to animal toxins or toxic peptides such as snake, scorpion, spider and bee venoms, toxic polyamines, and toxic peptides or other materials or substances released during bacterial infection (such as bacterial endotoxins and exotoxins), or during protozoal, fungal or viral infection.

Secondly, the specification at page 9, lines 12-15, defines the term "inhibition" to broadly include full or partial inhibition or suppression of the toxic effect of the toxic material or

substance in a human or non-human animal patient; the specification further defines the term to encompass both prophylactic and therapeutic treatment.

- **State of the prior art**

According to applicants' admitted prior art, compositions that are administered to inhibit the activity of toxic materials or substances are well known I the art to skilled artisans (page 9, lines 23-26 of the instant specification.

- **The predictability or lack thereof in the art**

Pharmaceutical formulation is unpredictable and the state of the prior art requires screening *in vitro* and *in vivo* to determine which inhibition of activities of the various toxins. In this effort a representative sample of each of the classes of agents listed in the specification may be is necessary to determine the effect of the dendrimer on these toxins. There is no absolute predictability even in view of the seemingly high level of skill in the art. Although, the specification states that these formulations are well known, applicants' have equated prophylaxis/preventing with inhibition and there is no pharmaceutical formulation that would make the infection or the effect of the toxins form happening. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face. The instant claimed invention is highly unpredictable as discussed below:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher,* 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statue. Further, their mode of action is often unknown or very

unpredictable and administration of the dendrimers can be accompanied by undesirable side effects.

Thus, in the absence of a showing of correlation between all animal toxins or toxic peptides such as snake, scorpion, spider and bee venoms, toxic polyamines, and toxic peptides or other materials or substances released during bacterial infection (such as bacterial endotoxins and exotoxins), or during protozoal, fungal or viral infection and dendrimer, one of ordinary skill in the art would be unable to fully predict possible results from the administration of the dendrimer due to the unpredictability all the materials disclosed as toxins.

In light of the preceding, it is not predictable that all the activity of all the claimed toxins would be inhibited/prevented from happening. It would be undue experimentation for the artisan to practice the full scope of the claimed invention without undue experimentation.

- **Amount of direction and guidance provided/present**

The guidance/direction provided is limited to cobra and bee venom and this guidance provided by the instant specification does not extend to representative toxins from other classes toxins claimed.

- **Presence or absence of working examples**

The working examples provided by the instant specification are clearly limited to one limited toxins from limited sources as discussed immediately above, no other class/species of representative toxins is exemplified or disclosed. It would therefore require undue experimentation to practice the full scope of the claimed inhibition of toxins of biological (animal, plant, microbial or viral) origin, including but not limited to animal toxins or toxic peptides such as snake, scorpion, spider and bee venoms, toxic polyamines, and toxic peptides or other materials or substances released during bacterial infection (such as bacterial endotoxins and exotoxins), or during protozoal, fungal or viral infection.

- **Breadth of claims**

"Inhibiting the activity of toxic material" is broadly claimed while the specification describes by exemplification toxins from the narrow species of cobra and bee.

- **Quantity of experimentation needed**

Since the formulation art is unpredictable as to the composition of the formulation as discussed under the predictability or lack thereof, it would require the artisan to engage in undue experimentation determine the inhibitory/preventative effect of the dendrimer on the claimed toxins.

Thus, the specification fails to provide sufficient support for the broad inhibition/prophylaxis of all toxins and toxic peptides from all animals, plant, microbial, bacterial, protozoan and fungal infections

Claim Rejections - 35 USC § 102

3. The rejection of claims 1-11 under 35 U.S.C. 102(b) as being anticipated by Matthews et al. (WO 95/34595) is withdrawn in view of the amendment excluding viral infections. The rejection may be brought back is further amendment to the claims include viral infection.

Double Patenting

4. The rejection of claims 1-11 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-36, 38 and 39 of U.S. Patent No. 6,190,650 is withdrawn in view of the amendment to the claims excluding viral infections. The rejection may apply if the claims include viral infection.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bundle et al. (US 6,310,043) and Tomalia et al. (US 5,338,532).

Bundle discloses treating bacterial infection with compounds that bind toxins (abstract); Bundle discloses that because various toxins are known to bind to reducing sugars, toxins can often be bound to solid supports containing immobilized reducing sugar (column 4, lines 58-60); furthermore, Bundle discloses that dendrimers, including multiple carbohydrate moieties have high affinity for the lecithin on the surface of bacteria (column 5, lines 11-19).

Tomalia discloses that PAMAM dendrimers bind to toxins (abstract; column 2, column 4, line 9; column 5, line 28, column 6, line 15; column 7, line 17; column 8, lines 21 and 22; Table II).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the polysaccharide containing dendrimer to treat bacterial infection as suggested by Bundle. One having ordinary skill in the art would have been motivated to use the dendrimer of Tomalia to treat bacterial infection with the expectation that the dendrimer would bind the toxic material released by the bacteria from the bacterial infection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
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